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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,526	02/26/2004	Kenneth W. Dobie	BIOL0002US	9932

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EXAMINER	
EPPS FORD, JANET L	

ART UNIT	PAPER NUMBER
1633	

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01/09/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/789,526

Applicant(s)

DOBIE ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-7, 9, 13, 20-23, 46, 47, 50, 52-62 and 66-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 13, 50, 52-59, 61, 62, 66 and 67 is/are allowed.
- 6) ☒ Claim(s) 4-7, 9, 20-23, 46, 47, 60 and 68-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-27-07 has been entered.
2. Claims 1, 4-7, 9, 13, 20-23, 46-47, 50, 52-62, and 66-73 are pending for examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

Double Patenting

4. The rejection of claims 1, 3-6, 13, 20-23, 46-47, 50-57 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 17-23 of copending Application No. 10/927,466 in view of Dobie et al., is withdrawn in response to Applicant's cancellation of claims 1-23 in the copending application.
5. The objection of Claim 58 under 37 CFR 1.75 as being a substantial duplicate of claim 13 is withdrawn in response to Applicant's amendment to claim 58.

Claim Rejections - 35 USC § 102

6. The rejection of claim 1, 4-6, 20, and 63 under 35 U.S.C. 102(b) as being anticipated by Olek et al. (WO 2001077384 A2 (German)), is withdrawn in response to Applicant's amendment to the claims requiring at least 95% complementarity with SEQ ID NO: 4.

Claim Rejections - 35 USC § 103

7. The rejection of claims 1, and 20-23 under 35 U.S.C. 103(a) as being unpatentable over Olek et al. in view of Bennett et al. (US Patent No. 5,968, 748) is withdrawn in response to Applicant's amendment.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 46-47, and 60 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, the prior rejection of these claims is withdrawn, and a new grounds for rejection is set forth below. It is noted that the rejection of claims 64-68 under 35 USC 112, 2nd, is withdrawn in response to Applicant's amendment.

10. Claim 46 and those claims dependent therefrom, claims 47 and 60 recite "the compound of claim 1, wherein said compound comprises the nucleobase sequence of SEQ ID NO: 19 and further comprises a ten deoxynucleotide region on both the 5' and 3' ends with at least five 2'-O-(2-methoxyethyl) nucleotides." The metes and bounds of

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this phrase are vague and indefinite since it is unclear if the recited additional deoxynucleotides are intended to refer to the portion of the compound that comprises the nucleobase sequence of SEQ ID NO: 19, or if the ten additional deoxynucleotides are intended to be a separate sequence. The same question is posed in regards to the additional at least five 2'-O-(2-methoxyethyl) nucleotides that flanks the 10 deoxynucleotide region, is intended to be a part of the portion of the compound that comprises the nucleobase sequence of SEQ ID NO: 19, or if the additional nucleotides comprise a different sequence.

11. Claims 70-73 are also rejected for the same reasons that claims 46-47 and 60 are rejected. Again, claims 70 and 73 recite wherein the claimed compound **further comprises** a region of deoxynucleotides that are flanked by a region of 2'-O-(2-methoxyethyl) nucleotides. Again, the scope of the claimed compounds are uncertain since it is unclear if the region of deoxynucleotides and the region of the 2'-O-(2-methoxyethyl) nucleotides are intended to be encompassed within the range of nucleotides that consists of the nucleobase sequence of SEQ ID NO: 19 (as recited in claim 70), or that comprises an at least 8 consecutive nucleobase portion and is at least 95% complementary with SEQ ID NO: 4. The exact sequence composition of these additional deoxynucleotides and 2'-O-(2-methoxyethyl) nucleotides is uncertain.

12. Claims 4-7, 9, 20-23, and 68-69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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13. Claim 4, and those claims dependent therefrom recites: "[T]he compound according to claim 1 comprising an oligonucleotide. " The metes and bounds of the claimed compound are vague and indefinite since it is unclear if the claimed compound is limited to wherein the compound is an oligonucleotide, or if the claimed compound further encompasses or further comprises an oligonucleotide of unknown sequence, structure or composition, including oligonucleotides comprising RNA, DNA, PNA, or etc., and combinations thereof. If the latter interpretation is correct then the scope of claim 4 fails to further limit claim 1.

Claim 5 recites wherein the oligonucleotide of claim 4 is a single-stranded oligonucleotide, Claim 6 recites the compound according to claim 4 in which the oligonucleotide is a DNA, and claim 7 recites wherein the oligonucleotide is a RNA oligonucleotide. As stated above. The metes and bounds of the single stranded oligonucleotide, DNA oligonucleotide or RNA oligonucleotide are vague and indefinite since it is unclear if the claims are intended to encompass wherein the compound as recited in claim 1 is limited to an oligonucleotide of DNA or RNA, or if the claims are intended to read on a compound according to claim 1 further comprising a DNA or RNA oligonucleotide. If the latter interpretation is correct then the scope of these claims fails to further limit claim 1 as well.

Moreover, claim 9 recites the compound of according to claim 7 wherein said compound is a short interfering RNA (siRNA) molecule, as stated in the rejection of claim 7, since the exact nature of claim 7 is uncertain the metes and bounds of claim 9 are uncertain as well. For example, it is unclear if the scope of claim 9 is intended to

read on an siRNA compound and further comprising an additional RNA oligonucleotide, or if the entire scope of the compound recited in claim 9 is intended to read on a single RNA oligonucleotide that functions as an siRNA (i.e. hairpin).

Claims 20-23 also fail to further limited claim 1, such that the scope of these claims are vague and indefinite to the extent that it is unclear if the recited modifications are intended to be a part of the original compound recited in claim 1, or if the recited modifications read beyond the scope of the original compound. For example, it is unclear if the recited modified nucleobases are intended to be a part of the compound of claim 1, or if they are intended to be an additional part of the claimed compound.

Claims 68-69 recite "the compound of claim 67, *further comprising a region of deoxynucleotides flanked on both the 5' and the 3' ends of said region with at least one 2'-O-(2-methoxyethyl) nucleotide..*". Again as stated above the exact structure of the additional deoxynucleotides and 2'-O-(2-methoxyethyl) nucleotides are uncertain. Applicants are requested to clarify if these additional structures are apart of the original compound recited in claim 50, of these additional regions read beyond the structure of the nucleic acid molecule recited in claim 50.

Conclusion

14. Claims 1, 13, 50, 52-59, 61-62, and 66-67 are allowable.
15. Claims 4-7, 9, 20-23, 46-47, 60, and 68-73 are rejected for the reasons set forth above.

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16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
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JLE